9.0 510(K) Summary

K073110

510(k) SUMMARY

9.1 Trade/Proprietary Name: Merits E600 Series Stair Lift

9.2 Common/Usual Name: Stairway Chairlift

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9.3 Classification Name: Powered patient transport

9.4 Comparison to Currently Marketed Devices

The Merits E600 Series Stair Lift is substantially equivalent to the Bruno Electra-Ride II Indoor Straight Rail Stairlift Model SRE-1550 (K033752)

9.5 Device Description

The Merits E600 Series Stair Lift basically consists of an upholstered chair assembly, a truck assembly, and a maximum 16 feet track. The chair and truck assemblies constitute the platform moving up and down along the inclined track. The entire lift is installed in either side of the indoor stairway in a private residence. All models share the same specifications such as driving means and safeties other than the power source. The Model E600 uses the AC power as its power source while the Model E601 employs the batteries and chargers. The operation of the lift is controlled by a momentary rocker control under one armrest and two infrared remote controls. The move of the lift will stop immediately when the button or switch of the controls is released.

9.6 Intended use

The Merits E600 Series Stair Lift System is a Powered Patient Transport, also commonly known as a Stairway Chairlift, or Stairlift. It is a motorized device intended for medical purposes to assist transfers of patients, or mobility-impaired persons, up and down flights of stairs.

9.7 Technological Characteristics

Merits E600 Series Stair Lift is equivalent in functions to the legally marketed predicate device. They all use rack and pinion as its driving and support means. This kind of means offers self-locking mechanism to prevent uncontrolled movement. The application of rack and pinion is well-established and has been extensively used by other legally marketed products. There is no technology difference between the two. For the remote control, Merits E600 Series Stair Lift adopts infrared light to achieve the controlling needs. Unlike radio signals used by the predicate, the infrared technology eliminates the possible interference or damage to the environment. The technology is not only safer than the radio frequency technology but also widely used by other products.

9.8 Performance Data

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

9.9 Conclusion

Based on the design, performance specifications, testing, and intended use, the Merits E600 Series Stair Lift is substantially equivalent to the legally marketed device, Bruno Electra-Ride II Indoor Straight Rail Stairlift Model SRE-1550 (K033752)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Merits Health Products Co., LTD.
c/o Mr. Steve Chao
No. 9, Rd. 36, Taichung Industrial Park
Taichung City
China (Taiwan) 40768

Re: K073110
Trade/Device Name: Merits E600 Series Stair Lift
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: Class II
Product Code: ILK
Dated: January 4, 2008
Received: January 4, 2008

Dear Mr. Chao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number:

Device Name: Merits E600 Series Stair Lift

Indications For Use:
The Merits E600 Series Stair Lift System is a powered patient transport, also commonly known as a Stairway Chairlift, or Stairlift. It is a motorized device intended for medical purposes to assist transfers of patients, or mobility-impaired persons, up and down flights of stairs.

Prescription Use_____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k073

Concurrence of CDRH, Office of Device Evaluation (ODE)